

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, *et al.*

Defendants.

Civil Action No. 3:17-01362

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, *et al.*

Defendants.

Civil Action No. 3:17-01665

**MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE
MARKETING OPINIONS OF ANNA LEMBKE, KATHERINE KEYES,
ANDREW KOLODNY, AND JAKKI MOHR**

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INTRODUCTION¹

Roughly one year ago, when Plaintiffs filed their Third Amended Complaint, they named as defendants 48 *manufacturers* of prescription opioids (or officers and directors of those companies). Plaintiffs alleged that those manufacturers are the root cause of the opioid crisis because of their alleged “pervasive” and “deceptive” marketing scheme that “convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven.” Cabell County Commission and City of Huntington Third Amended Complaint, ECF No. 2582 (filed at No, 17-md-2804, N.D. Ohio prior to remand) at ¶¶ 347.

Plaintiffs did not allege that Distributor Defendants engaged in these “deceptive” marketing activities that “convinced health care providers” that the risks of prescription opioids were “overblown and that the benefits ... were proven.” The Complaints make only a passing reference to so-called distributor marketing, *id.* ¶¶ 1129, 1130, and until recently, none of plaintiffs’ experts in the opioid litigation offered any opinions about distributor marketing.² But now that Distributors are the only defendants in this trial, Plaintiffs are attempting to read Distributors into their marketing allegations. Plaintiffs’ efforts to cobble together expert testimony to support their late-breaking marketing theory fails for several reasons.

¹ Marketing causation was the subject of a *Daubert* motion filed in the MDL Court. Judge Polster granted the *Daubert* motion in part. *In re: National Prescription Opiate Litig.*, MDL 2804, Case No. 1:17-md-2804, Doc. 2549 at 1 (N.D. Ohio Aug. 28, 2019) (“MDL Ruling”) (Exhibit *). Judge Polster ruled that two of the same experts at issue here, Anna Lembke and Katherine Keyes, were not qualified to offer expert opinions on marketing activities. And while Andrew Kolodny was not identified as an expert in Track 1, Judge Polster’s rationale for precluding marketing testimony from Keyes and Lembke applies to him as well.

² Although not the focus on this motion, Defendants dispute Plaintiffs’ experts’ characterization of their activities as “marketing.”

Plaintiffs offer three experts—Anna Lembke (a psychiatrist), Katherine Keyes (an epidemiologist) and Andrew Kolodny (a doctor)—who are entirely unqualified to offer expert opinions on Distributors’ marketing activities or marketing causation—that is, the theory that Distributors engaged in a marketing campaign to expand and maintain the market for opioids, which impacted prescribing practices and led physicians to overprescribe these medications. The MDL court concluded that Lembke and Keyes do not have the expertise to permit them to offer opinions on marketing activities. MDL Ruling at 1. That conclusion was correct and nothing has changed to improve Lembke or Keyes’ qualifications. The same conclusion also applies equally to Kolodny, a doctor who likewise lacks any education or experience in marketing. For this reason alone, the Court should preclude Lembke, Keyes and Kolodny from providing opinions on marketing activities or causation.

Furthermore, none of these experts—nor Plaintiffs’ other purported marketing expert, Jakki Mohr—has any methodology (much less a reliable one) to support a conclusion that Distributors’ purported marketing activities deceived or misled doctors about the risks and benefits of prescription opioids. For instance, none did *anything* to determine if doctors or pharmacies received or relied on any purported distributor marketing materials. In fact, Mohr (who as a marketing professor has general expertise that Keyes, Lembke and Kolodny lack, though none in pharmaceutical marketing) specifically said she was *not* opining that any of Distributors’ purported marketing activities were misleading or deceptive, and she had no opinion that doctors and other prescribers were misled or deceived by anything Distributors did.

Finally, the opinions offered by these experts on marketing-related issues do not “fit” the facts of this case, as required to pass muster under Rule 702 and *Daubert*. This case was brought by—and seeks recovery on behalf of—Cabell County and the City of Huntington based on alleged

harms in those jurisdictions, yet *none* of these experts focused their analyses on Cabell County and the City of Huntington. None could identify any of Distributors' purported marketing materials or activities that occurred in Cabell County or the City of Huntington. They merely *assumed*, without a factual basis, that those activities took place in Cabell County and Huntington. None evaluated whether any of these purported marketing activities actually occurred in Cabell County and the City of Huntington.

For all of these reasons, and as further explained below, the Court should exclude these experts from testifying on Distributors' marketing and promotional activities.

EXPERT QUALIFICATIONS AND OPINIONS

A. Anna Lembke

Lembke is a medical doctor with expertise in addiction and pain, Exhibit A, Lembke Report at 1; MDL Ruling at 1, who offers the following marketing causation opinions:

- “The addictive nature of medicinal opioids has been known for centuries. The Pharmaceutical Opioid Industry’s³ misrepresentations of the safety and efficacy of prescription opioids reversed a century of appropriate restrictions on the use of these dangerous drugs, and substantially contributed to the current opioid epidemic.” *Id.* at 7.
- “The Pharmaceutical Opioid Industry contributed substantially to the paradigm shift in opioid prescribing through misleading messaging about the safety and efficacy of prescription opioids. The Industry disseminated these misleading messages through key opinion leaders, medical school curricula, continuing medical education courses, clinical decision support tools, professional medical societies, the Federation of State Medical Boards, and the Joint Commission.” *Id.* at 8.

³ “Pharmaceutical Opioid Industry” is a term Plaintiffs and their experts recently began using in connection with their efforts to include distributors within their marketing theories. Lembke testified at the recent *Frye* hearings in New York that the term did not include distributors. See Exhibit K, Minutes of Frye Hearing: Testimony of Dr. Lembke, *In re: Opioid Litigation* (Index No.: 400000/2017), Supreme Court of the State of New York, County of Suffolk: Part 48, at 160:15-161:17; 162:13-20.

- “Opioid distributors collaborated with opioid manufacturers and pharmacies to promote sales of opioid pain pills. Such coordinated efforts included programs to give away free samples of opioids; coupons to discount opioids; and promotion of specific opioid products under the guise of education. These activities increased the population of opioid users, dose and duration of opioid use, and the risk of opioid misuse, addiction, dependence, and death.” *Id.*

B. Katherine Keyes

Keyes is an epidemiologist Ph.D who specializes in substance use and substance use disorders, Exhibit B, Keyes Report at 4; MDL Ruling at 1, and who offers the following opinions regarding marketing causation:

- “The increase in opioid prescribing was driven by a multitude of factors, including direct marketing to physicians using data that underestimated opioid use disorder risks in patients Evidence shows that pharmaceutical marketing of prescription drugs increases prescribers’ likelihood of prescribing the marketed drug in the future.” Keyes Report at 14.
- “The supply of opioids was also facilitated by pharmaceutical promotional activity to physicians.” *Id.* at 29.

C. Andrew Kolodny

Kolodny is a medical doctor whose clinical specialty is the treatment of opioid use disorder, Exhibit C, Kolodny Report at 3, and who offers the following marketing causation opinion:

- “Defendants worked to dramatically expand and then maintain the market, the demand and, therefore, the supply of prescription opioids through participating in a massive marketing and misinformation campaign about opioids.” *Id.* at 2.

D. Jakki Mohr

Mohr is a professor with a Ph.D in marketing, Exhibit D, Mohr Report at 2. She opines that Distributors engaged in “marketing activity,” but she testified that she has no opinion that any of that activity was false or misleading, Exhibit H, Mohr Dep. at 133:6-134:13, or what the impact of that activity was on the overall level of prescription opioids. Mohr Dep. at 129:14-21 (“Q. So, Doctor Mohr, I just wanted to ask to be clear, you did not attempt to quantify the impact of the distributor marketing services in any way; correct? A. Yes, as I said, that was not the task that I

was asked to perform.”) (objection omitted). Instead, according to Mohr, “my task was to answer the question of whether or not distributors engaged in marketing. And the answer to that is clearly, yes.” *Id.* at 126:17-19; *see also id.* at 130:13-17.

LEGAL STANDARD

Courts have the responsibility to play a “gatekeeping role” with respect to experts. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 595, 597 (1993). In performing this role, courts first must evaluate whether a witness is “qualified as an expert.” Fed. R. Evid. 702. Courts additionally must ensure “that an expert’s testimony both rests on a *reliable* foundation and is *relevant* to the task at hand.” *Daubert*, 509 U.S. at 597 (emphasis added).

“A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.” *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 249–50 (4th Cir. 1999) (citing *Daubert*, 509 U.S. at 590, 592–93). Courts may consider several factors in assessing reliability, including: (1) whether the expert’s theory or technique has been or can be tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and 5) whether the theory is generally accepted. *Daubert*, 509 U.S. at 593–94.

Relevant expert evidence is evidence that helps “the trier of fact to understand the evidence or to determine a fact in issue.” *Daubert*, 509 U.S. at 591. The proposed expert testimony must have “a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Id.* at 592. “The consideration has been aptly described ... as one of ‘fit.’” *Id.* at 591; *Garlinger v. Hardee’s Food Sys., Inc.*, 16 F. App’x 232, 235 (4th Cir. 2001) (“The consideration of relevance requires the district court to determine whether the testimony ‘fits’ the

instant case.”). On the question of relevance or fit, courts recognize that an expert’s “testimony must be sufficiently tied to the facts of the case that it will be of assistance to the factfinder in resolving a disputed fact.” *Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co., Inc.*, 189 F. Supp. 2d 482, 495 (S.D. W. Va. 2002) (citing *Kumho Tire Co. v. Charmichael*, 526 U.S. 137, 150 (1999)). In other words, to “fit” the facts of the case, there “must be a valid ... connection to the pertinent inquiry before testimony is admissible.” *Id.* (internal quotation marks omitted).

In the bench trial context, where a judge rather than a jury sits as the factfinder, Rule 702 plays no less an important part in the consideration of expert testimony. *See UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832–33 (3d Cir. 2020) (recognizing that “Rule 702 applies whether the trier of fact is a judge or a jury,” and noting that “the failure to conduct any form of ‘assessment’ of an expert and the proposed testimony before admitting the testimony is an abuse of discretion”); *see also Kumho Tire*, 526 U.S. at 152, 158–59 (Scalia, J., concurring) (explaining that while district courts retain “latitude” to decide “how” to apply these requirements in a bench trial, that “is not discretion to abandon the gatekeeping function” or “perform the function inadequately. Rather, it is discretion to choose among *reasonable* means of excluding expertise[.]”).

ARGUMENT

I. Lembke, Keyes, And Kolodny Are Not Qualified To Give Opinions On The Causative Effect Of Distributor Marketing.

As a threshold matter, three of Plaintiffs’ experts are not qualified to give an opinion on Distributors’ alleged marketing activities, or the impact of those activities, because they have no expertise in marketing. To opine as to marketing and its effects, an expert must have specialized expertise and experience in marketing. *See, e.g., In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 633, 638 (4th Cir. 2018) (affirming

exclusion of expert statistician who “was simply not qualified to make determinations about which patients’ data should have alerted Pfizer to a possible association between its drug and diabetes” because he “readily admitted that he had no expertise in diabetes”); *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-CV-144, 2015 WL 13022172, at *11 (S.D. Ohio Oct. 2, 2015), *aff’d*, 680 F. App’x 369 (6th Cir. 2017) (striking expert’s testimony regarding pharmaceutical manufacturer’s marketing because he “lacks marketing and regulatory expertise and therefore would not be an appropriate expert to opine” on manufacturer’s promotion).

Neither Lembke, Keyes nor Kolodny has any specialized knowledge as to marketing generally, let alone pharmaceutical marketing. In the MDL, Judge Polster addressed this issue with respect to Lembke and Keyes and ruled that they lacked the qualifications to testify on marketing activities or marketing causation. On Lembke, the Judge Polster concluded:

Lembke is highly distinguished as a medical expert in the scientific disciplines of psychiatry, addiction, and pain. She is therefore “fully qualified” to opine on matters involving medical facts and science that fall within these areas. However, Plaintiffs have not shown Lembke has specialized training, knowledge, or experience in the field of pharmaceutical marketing.

MDL Ruling at 11 (citations omitted). Similarly, on Keyes, Judge Polster stated:

As an epidemiologist, Keyes clearly has specialized training and expertise in statistical analysis and the determination of factors that play a role in producing opioid-related harm. The record, however, does not show that her expertise in the scientific field of epidemiology includes the determination of marketing factors that contributed to the increased supply in prescription opioids.

Id. at 20.

That reasoning applies with equal force here. Lembke still lacks specialized knowledge of pharmaceutical marketing. As she admitted during her deposition, she has no degree in marketing, Exhibit E, Lembke Dep. at 122:5–9, and has written only one publication—a book titled *Drug Dealer, M.D.*—that purportedly relates to marketing (but not pharmaceutical distributor marketing), *id.* at 122:13–123:7; 159:7–22. Lembke has no education in marketing and did not

take any marketing classes prior to writing her book. *Id.* at 124:8–10. Addressing Lembke’s book, Judge Polster correctly recognized that it shows “no specialized training or experience by Lembke in the field of pharmaceutical marketing and/or its effect on prescribing practices, or the field of economics.” MDL Ruling at 11. Judge Polster also correctly rejected the argument that Lembke’s review of scientific literature on marketing qualifies her to opine on marketing because “a person does not become an expert in an area outside of her regular field merely by ‘reading up’ for the specific purpose of testifying.” *Id.* at 11 n.5 (quoting *In re Welding Fume Prod. Liab. Litig.*, No. 1:03-cv-17000, MDL 1535, 2005 WL 1868046, at *35 (N.D. Ohio Aug. 8, 2005)).

The same goes for Keyes—she still lacks any education or experience in marketing. As Judge Polster recognized, Keyes has specialized knowledge as an epidemiologist, but that specialized knowledge has *nothing* to do with pharmaceutical marketing or the effect of pharmaceutical marketing on physician prescribing. MDL Ruling at 20. At her deposition, Keyes unsurprisingly disclaimed knowledge of distributor marketing, stating “I am aware that distributors engage in opioid marketing in general, and I don’t preclude that from occurring. But I’m – that’s not what I evaluate in my report, and I don’t offer an opinion on it.” Exhibit F, Keyes Dep. 279:2–6.

Kolodny suffers from the same lack of relevant credentials and experience in marketing. Kolodny does not have any formal education in marketing. Exhibit G, Kolodny Dep. at 198:25–199:11. His only personal experience with marketing involved leading an effort on behalf of New York City’s Health Department to reach out directly to doctors about the benefits of buprenorphine, *id.* at 199:12–200:16, a type of marketing Kolodny admits is done by manufacturers and not distributors, *id.* at 218:8–15, and thus he had never encountered distributor promotional activity outside of this litigation. Kolodny’s first introduction to alleged marketing by distributors was in

this litigation, based on a review of documents given to him by Plaintiffs’ attorneys. Kolodny Dep. at 205:5–14. Indeed, before he began working with the attorneys on this case, Kolodny “had no idea that distributors marketed, promoted, advertised opioids” *Id.* at 207:25–208:5. Thus, while Kolodny may have “read up” about alleged distributor marketing at the request of Plaintiffs’ counsel, that does not make him an expert in the topic. MDL Ruling at 11 n.5 (quoting *In re Welding Fume Prod. Liab. Litig.*, 2005 WL 1868046, at *35).

In sum, Lembke, Keyes and Kolodny lack any specialized expertise that qualifies them to offer opinions on Distributors’ marketing activities or marketing causation. Fed. R. Evid. 702. They should be precluded from testifying on this subject for this reason alone.

II. Lembke, Keyes, Kolodny, And Mohr Fail To Offer Admissible Expert Opinions On Distributor Marketing Causation.

The Court need go no further than the lack of qualification to exclude the marketing-related opinions of Lembke, Keyes and Kolodny. But, in addition, their opinions are flawed for additional reasons beyond the lack of qualification.

First, each fails to offer an opinion based on a reliable methodology that Distributors’ so-called marketing activities affected the levels of prescribing for opioid medicines. Plaintiffs’ other expert, Mohr, does not offer an opinion that these asserted marketing activities were false or misleading or had any effect on prescribing. She readily acknowledged that she is not offering any expert opinions as to the degree that so-called marketing activity by Distributors contributed to opioid sales or levels of prescribing, or how that compares to other factors that contributed to opioid sales or levels of prescribing. Mohr Dep. at 129:14-21

Second, Lembke, Keyes, Kolodny and Mohr each fail to offer a relevant opinion that “fits” the facts of this case.

A. Plaintiffs' Experts Fail To Offer Reliable Opinions That Distributors' Alleged Marketing Activities Affected Prescribing For Opioid Medicines.

Lembke, Keyes and Kolodny all offer the conclusion, without any methodology beyond their say-so, that Distributors engaged in marketing activities that affected prescribing decisions by doctors. But this entirely unreliable and is based on nothing more than their *ipse dixit* statement of a conclusion. “A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.” *Oglesby*, 190 F.3d at 249–50 (citing *Daubert*, 509 U.S. at 590, 592–93). None of these experts base their opinions on scientific, technical, or other specialized knowledge. None can support a claim that their theory/technique has been or can be tested, has been subjected to peer review and publication, has a low error rate, is subject to standards or controls, or is generally accepted. *See Daubert*, 509 U.S. at 593–94. Indeed, these experts employed no real methodology at all, and their methods present very basic problems that undermine any conclusion they are reliable.

First, none of these experts did *anything* to determine if doctors or pharmacies received or relied on any purported distributor marketing materials. They do not know whether (i) any Distributor disseminated any marketing material; (ii) whether any doctors saw any such marketing materials; or (iii) whether any doctors relied on the materials in writing any opioid prescription. Lembke Dep. at 171:19–172:1; 172:20–23; 297:4–9; Keyes Dep. at 20:8–11, 143:9–10; Kolodny Dep. at 261:3–14; Mohr Dep. at 140:2–6, 156:1–6, 17–22.

Each of these experts therefore can only speculate about whether Distributors' so-called marketing activities had any impact on doctors. As such, they cannot reliably say whether any alleged Distributor marketing impacted physician prescribing. Thus, they should be precluded from giving any opinion on marketing causation. *See In re Actos® (Pioglitazone) Prod. Liab.*

Litig., No. 6:11-MD-2299, 2014 WL 12653759, at *13 (W.D. La. Jan. 14, 2014) (excluding marketing causation opinion because expert laid no foundation for knowing “what a physician or consumer *actually might have known or done*” and that finding that “what a doctor or consumer *might actually* have believed or *actually done* is, without question, outside her purview”); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *12 (E.D. Pa. June 20, 2000) (“The court can easily preclude, from a *Daubert* viewpoint, the rendering of opinions by either of these witnesses ... as to what doctors in general think, because the witnesses are not qualified for that.”).

Second, none of these experts identifies any marketing activities by Distributors that went directly to doctors or other prescribers. For instance, Keyes stated that “the materials that I have seen on marketing to physicians has been -- has been with regard to *manufacturers*.” Keyes Dep. at 283:24-284:14 (emphasis added).

Third, while these experts purport to opine that distributor marketing caused an increase in the prescribing of opioid medicines, they readily acknowledged that other factors may have caused an increase in prescribing—such as the conduct of pharmaceutical manufacturers, decisions by the FDA, changes in the standard of care for the treatment of pain, and doctors’ judgments. Yet, none of them weighed the causal role of these other factors in affecting levels of prescribing. In disclaiming any opinion on the extent to which alleged distributor marketing contributed to the increase in prescribing, Mohr provided testimony that illustrates the problems with the causation opinions of the other experts. Mohr admits that she “can’t disentangle the total industry’s [e]ffect to look at distributors.” Mohr Dep. at 125:21-23. According to Mohr, “[t]hat would be an econometric study that would take some time to sort out. That was not in the scope of my task.” *Id.* at 126:4-10.

None of the other experts engaged in that task either. For instance, Lembke acknowledged other causative factors at play, including that “opioid *manufacturers* were wildly successful in duping doctors into prescribing large quantities of opioids to patients.” Lembke Dep. at 104:19–23 (emphasis added), 101:20–102:8. She also recognized that “the FDA label didn’t adequately communicate the degree of risk of addiction,” *id.* at 103:6–8, and that the Journal of the American Medical Association (JAMA) published materials that contributed to opioid sales, *id.* at 152:18–154:9. Nevertheless, Lembke does not even attempt to isolate and weigh the causal role of these other factors in comparison to distributor marketing. For example, she acknowledges that “one way to measure part of the influence on prescribing would be to look at how much money individual companies are spending on marketing efforts,” but admits that she has not attempted to undertake such an analysis for distributors in comparison to manufacturers. *Id.* at 230:2–24.

Kolodny is more of the same. He acknowledges that manufacturers made false marketing claims to influence opioid prescribing, Kolodny Dep. at 202:23–204:14, that the FDA failed to properly regulate manufacturers, *id.* at 207:5–12, and that the West Virginia Medical Board helped disseminate to doctors about the risks and benefits of prescription opioids, *id.* at 314:14–316:10. He acknowledged all of this in testimony before Congress as well:

“[T]he reason the medical community began prescribing so aggressively, is because we (doctors) were responding to a brilliant, multi-faceted marketing campaign that changed the culture of opioid prescribing. . . . We would have been less gullible if we were only hearing these messages from drug company sales reps. But we were hearing these messages from pain specialists, eminent in the field of pain medicine; we were hearing it from professional societies; from the Joint Commission, which accredits our hospitals; and we were hearing from the Federation of State Medical Boards—all of whom had financial relationships with opioid manufacturers.”

Andrew Kolodny, Statement for the Record (Jan. 17, 2018). But Kolodny makes no attempt to isolate and weigh the causal role of distributor marketing on prescribing activity in comparison to these factors. *See, e.g.*, Kolodny Dep. at 282:6–283:5.

Keyes, for her part, did not even try to isolate and weigh the various potential causes of changes in opioid prescribing. In fact, the underlying information on which Keyes relies relates entirely to *manufacturers*. She states: “I know that the distributors engaged in marketing activities with regard to opioid products. But I’m not -- *I haven’t evaluated the specifics of those marketing activities.*” Keyes Dep. at 276:4-7 (emphasis added). Thus, Keyes has no reliable basis for saying that Distributors’ so-called marketing activities had any impact on prescribing levels for opioid medicines. This, in turn, makes her opinion on Distributor marketing causation—as well as the others—entirely unreliable.

As this Court has held, an expert opinion cannot pass muster under Rule 702 and *Daubert* unless the expert takes account of factors that may undermine the reliability of his or her opinions. *See Salazar v. United States*, No. CIV. A. 5:01-0617, 2003 WL 25695854, at *3 (S.D.W. Va. Feb. 18, 2003) (Faber, J.) (excluding expert who “did not account for a possible alternative factual situation which would, if true, significantly affect the reliability of his opinion”); *Koger v. Norfolk S. Ry. Co.*, No. CIV.A. 1:08-0909, 2010 WL 692842, at *4 (S.D.W. Va. Feb. 23, 2010) (Faber, J.) (excluding expert who “despite acknowledging the significance of personal attributes in an analysis of this kind, ... did not consider these factors in reaching his conclusions”).

In short, none of these experts used reliable methods. None can support a claim that their theory/technique has been or can be tested, has been subjected to peer review and publication, has a low error rate, is subject to standards or controls, or is generally accepted. They reach conclusions about the impact of Distributors’ so-called marketing activities on prescribing levels without applying any methodology at all. They did not communicate with the prescribing physicians who allegedly were impacted by Distributors’ marketing, they have not reviewed Distributors’ purported marketing materials, and they have not weighed potential alternative

causes for changes in prescription rates. Thus, they cannot satisfy Rule 702 and *Daubert* with respect to reliability when it comes to distributor marketing causation.

B. Plaintiffs’ Experts Fail To Offer Relevant Opinions That Fit This Case.

Expert testimony is not admissible under *Daubert* unless it is relevant. Expert testimony has have “a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Daubert*, 509 U.S. at 592. “The consideration has been aptly described ... as one of ‘fit.’” *Id.* at 591. Lembke, Keyes, Kolodny and Mohr do not offer relevant opinions that fit this case.

First, and this applies to all of these experts, this case centers on Cabell County and the City of Huntington, yet *none* of these experts focused their analyses of Distributor marketing activities on Cabell County and the City of Huntington. None of the experts could identify materials that were sent to Cabell County or the City of Huntington—they merely *assumed*, without a factual basis, that the materials were sent to Cabell and Huntington. None took the time or effort necessary to analyze what was actually occurring in Cabell County and the City of Huntington.

Lembke is unaware of any doctor, pharmacy, or patient in Cabell County or the City of Huntington who received the promotions she analyzed. Lembke Dep. at 102:19–23; 128:3–7; 131:19–132:4; 146:24–147:4; 262:21–263:7; 273:4–9; 273:24–274:5; 275:3–6; 279:4–9; 281:6–9; 284:3–6; 296:23–297:9; 299:22–300:2. She has never interviewed doctors in Cabell County or the City of Huntington. *Id.* at 170:19–172:1; 172:20–23. Nor has she reviewed any orders that the distributors in this case shipped to pharmacies in Cabell County or the City of Huntington. *Id.* at 161:5–8.

The same is true for Keyes, who is unaware of any direct marketing to physicians by distributors in Cabell County or the City of Huntington. Keyes Dep. at 282:9-12. Keyes is not even aware of any direct marketing to physicians by distributors in West Virginia. *Id.* at 282:5-8.

As Keyes admits, “the materials that I have seen on marketing to physicians has been -- has been with regard to *manufacturers*.” *Id.* at 284:5-7 (emphasis added).

Kolodny is no different. He does not know whether any of the marketing materials he analyzed were actually disseminated in Cabell County or even West Virginia, Kolodny Dep. at 284:14–285:2, he cannot point to any evidence that any pharmacist in Cabell County or the City of Huntington ever received or considered the marketing materials he analyzed in deciding whether to make a purchase, *id.* at 285:3–286:3, and he has not conducted any survey or study on whether pharmacists—in Cabell County and the City of Huntington or otherwise—considered the materials he analyzed in deciding whether to make purchase, *id.* at 286:4–23.

Likewise, Mohr cannot point to any materials that went to Cabell County or the City of Huntington. Mohr Dep. at 132:24-133:5. Similarly, she has not studied the pharmacies in West Virginia, let alone Cabell County and the City of Huntington, Mohr Dep. at 31:23-32:5; 34:24-35:3.

Since none of these experts can identify marketing materials that went specifically to Cabell County and the City of Huntington, none of them can provide a relevant opinion as to the effect of any marketing materials in Cabell County and the City of Huntington.

Second, and this relates to Mohr specifically, an expert opinion on distributor marketing causation is not useful unless it actually addresses whether *distributor* marketing of opioids *caused* overprescribing. While Mohr opines in her report that distributor marketing “successfully enlarged the market for opioids and increased sales, Mohr Report at 6, that opinion is not the product of any methodology at all, let alone a reliable one. According to Mohr, with respect to distributors, “my task was to answer the question of whether or not distributors engaged in marketing. And the answer to that is clearly, yes.” Mohr Dep. at 126:17-19; *see also id.* at 130:13-17. Mohr made no

effort to quantify the impact of that distributor marketing, and does not have any expert opinion about the degree to which factors *other* than distributors' actions contributed to opioid sales. *Id.* at 129:14-21 (“Q. So, Doctor Mohr, I just wanted to ask to be clear, you did not attempt to quantify the impact of the distributor marketing services in any way; correct? A. Yes, as I said, that was not the task that I was asked to perform.”) (objection omitted). Since Mohr does not offer a reliable causation opinion related to distributors, her opinion is not relevant to distributor marketing causation.

With respect to the marketing analysis that Mohr does engage in, she does not distinguish between the marketing of opioids versus the marketing of non-opioids. As Mohr stated, “my task was to talk about the marketing services generally, and I did not divide them by which were opioid specific compared to other types of products.” Mohr Dep. 239:7-10. Thus, Mohr is unaware of the breakdown of opioids versus non-opioids in her marketing analysis, *id.* at 105:22-106:1;160:6-11, and she could not determine how many rebates the distributors used for opioids versus non-opioid medications, *id.* at 160:6-11.

“Helpfulness to the trier of fact is the touchstone of Rule 702.” *Koger*, 2010 WL 692842, at *1 (citing *Kopf v. Skyrms*, 993 F.3d 374, 377 (4th Cir. 1993)). But if Mohr can only speak to the existence of marketing without offering any opinions on how those activities affected prescribing levels for opioid medicines, her opinion is entirely unhelpful to the trier of fact.

III. Other Experts Who Have Made Statements About Distributor Marketing Causation Should Be Precluded From Testifying On The Topic.

Other experts for Plaintiffs who do not opine on distributor marketing and its causes nonetheless have made gratuitous statements on the topic during their depositions. These individuals—like Lembke, Keyes and Kolodny—lack qualifications and have no basis to claim a reliable or relevant opinion on the topic.

For example, Plaintiffs' expert David Courtwright is a historian who has no education or experience in marketing. Exhibit I, Courtwright Dep at 33:14–20; 96:20–97:5. He does not offer an opinion on distributor marketing causation in his report. Nonetheless, at his deposition, Courtwright made statements regarding what activities he believes to constitute distributor marketing. Courtwright Dep. at 77:8–78:18. But Courtwright admits that “I don’t consider myself to be an expert in marketing in general, no.” *Id.* at 97:4–5. In any event, like Mohr, Courtwright never ties his ruminations on what might constitute distributor marketing to anything about causation, and thus cannot provide a relevant opinion on the topic.

Additionally, Plaintiffs' expert Gordon Smith is an epidemiologist (like Keyes) with no education or experience in marketing. Exhibit J, Smith Dep. at 14:2-3. He does not offer an opinion on distributor marketing causation in his report. Nonetheless, at his deposition, Smith answered a question regarding distributor marketing causation and stated: “I know in the report, they talk about increased marketing of drugs, that they were marketed as being safe and less addictive or nonaddictive, particularly for people with chronic pain.” Smith Dep. at 89:13-21. However, Smith later made it clear that he was talking about manufacturer marketing. *Id.* at 90:13-16.(“Q. So the marketing behavior that you’ve just referenced is conducted by pharmaceutical manufacturers as opposed to distributors, correct? A. Correct.”) Smith thus not only lacks qualifications to opine on distributor marketing causation, he also lacks any opinion that could be considered relevant to the topic.

CONCLUSION

For the reasons above, Distributors request that the Court exclude Lembke, Keyes, Kolodny, and Mohr from testifying on the causative effect of distributor marketing. The Court should also exclude Courtwright and Smith from incorporating their gratuitous marketing statements into any testimony they give in this case at trial.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 2nd day of October, 2020, the foregoing Memorandum In Support Of Defendants' Motion To Exclude The Marketing Opinions Of Anna Lembke, Katherine Keyes, Andrew Kolodny, And Jakki Mohr was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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